<u>REMARKS</u>

This application has been reviewed in light of the Office Action mailed on May 21, 2003. Claims 1-58 are pending in the application with Claims 1, 44, 50 and 56 being in independent form. Claims 2, 3, 5, 7-13, 15-24, 26-31, 33-39, 43-49 and 53-58 have been withdrawn from consideration. By the present amendment, Claims 1 and 50 have been amended and Claim 59 has been added. No new matter or issues are believed to be introduced by the amendments.

In the Office Action, the Examiner correctly states that the listing of references in the specification is not a proper information disclosure statement. It is respectfully submitted that all of the references listed in the specification, except for two references, namely, U.S. Patent Nos. 3,765,606 and 4,294,407, have been cited in a properly filed information disclosure statement which the Examiner has acknowledged. A supplemental information disclosure statement is being filed concurrently with this amendment citing the two U.S. patents identified above which are listed in the specification and which have not been cited in an information disclosure statement. Applicant respectfully requests the Examiner to consider these two U.S. patents.

The Examiner states that new corrected drawings are required. It is respectfully submitted that the Applicant is filing formal drawings concurrently with the filing of this amendment.

Further, in the Office Action, the specification and Claims 50-52 were objected to. Claim 50 has been amended in a manner which is believed to obviate the objections to the specification and Claims 50-52. Accordingly, withdrawal of the objections is respectfully requested.

Claims 1, 4, 6, 14, 21, 23, 25 and 50-52 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,013,241 issued to von Gutfeld et al. on May 7, 1991 ("von Gutfeld et al.").

Applicant's invention as recited by independent Claims 1 and 50 is patentably distinct from the device disclosed by von Gutfeld et al. The tool disclosed by von Gutfeld et al. does not produce a spray using an ultrasonic transducer and, hence, does not deliver the spray onto a wound surface as stated on page 4, paragraph 8 of the Office Action. The tool disclosed by von Gutfeld et al., as further described below, sonicates liquid to create a sonicated jet stream (not a spray) for cleaning teeth as is known in the art. The sonicated jet stream is directed through tube 18 before being impinged upon teeth to be cleaned.

Even if the tool disclosed by von Gutfeld et al. did produce a spray, the spray would not have been directed away from the tool, since individual spray droplets would have impinged upon the inner surface of the tube 18, thereby causing the spray to morph into a liquid flow.

Only Applicant has realized a nozzle and apparatus, as disclosed by original independent Claims 1 and 50 and new independent Claim 59, for producing a spray utilizing an ultrasound transducer, and for delivering the spray to an external environment, i.e., delivering the spray outside the nozzle and apparatus.

Nonetheless, Applicant has amended independent Claims 1 and 50 in a manner which is believed to structurally and further patentably distinguish Applicant's invention over the tool disclosed by von Gutfeld et al. Claim 1 has been amended to recite:

A nozzle for ultrasound wound treatment, for producing a spray of liquid using an ultrasound transducer tip, directing and delivering said spray onto the wound surface, comprising: a main body having a proximal end that removably attaches to an ultrasound transducer, said main body also having a distal end which is marginally close to a free distal end of the ultrasound transducer tip, said distal end of said main body having a gap with said distal end of said ultrasound transducer tip, said distal end of main body being coaxially placed about the said ultrasound transducer tip, said main body being connected with at least one reservoir, for holding and delivering a wound treatment solution to the distal end or the marginally close

radial side of said ultrasound transducer tip <u>via an opening substantially aligned with</u> the free distal end of the ultrasound transducer tip. (Emphasis added)

Claim 50 has been amended to recite similar recitations as the recitations added to Claim 1.

von Gutfeld et al. does not disclose or suggest at least the newly added limitations to Claims 1 and 50. von Gutfeld et al. is directed to an ultrasonic jet dental tool and method for removing plaque from teeth and for cleaning teeth. Ultrasonic energy is coupled into a liquid stream to sonicate the liquid stream and create a sonicated jet stream (not a spray) that is delivered to teeth to be cleaned. The tool includes a reservoir 10 containing a liquid, means for creating a liquid stream 14, and a transducer means 16 for creating ultrasonic energy for sonicating the liquid stream to create a sonicated (or sonified, as described by von Gutfeld et al.) jet stream. A housing 20 is included for containing the liquid, a nozzle 22 from which the sonicated jet stream (not a spray) exits, tubing 24 for delivering the liquid from the reservoir 10 to the housing 20, and a pump 26 for moving the liquid from the reservoir 10 to the housing 20 and the nozzle 22.

The transducer means 16 is contained within the housing 20 where it is immersed in liquid. This is structurally different from Applicant's nozzle and apparatus as recited by Claims 1 and 50, where the transducer is not immersed in liquid, and a wound treatment solution or fluid is delivered to a distal end of an ultrasound transducer tip or a distal radiation surface of a transducer.

Further, the tool disclosed by von Gutfeld et al. does not create a spray from the liquid using the transducer means 16, let alone, deliver the spray to the teeth. Further, in the tool

disclosed by von Gutfeld et al., a distal opening of the tubing 24 is not substantially aligned with a distal tip or radiation surface of the transducer means 16. Therefore, the tubing 24 delivers the liquid to the housing 20 behind the distal tip or the radiation surface of the transducer means 16 to fill the housing 20 with liquid and immerse the transducer means 16 therein.

Accordingly, von Gutfeld et al. does not disclose or suggest pre-existing limitations of Claims 1 and 50 and the newly added limitations to Claims 1 and 50. Specifically, von Gutfeld et al. does not disclose or suggest the housing or main body being connected with at least one reservoir, for holding and delivering liquid or a wound treatment solution to a distal end or a marginally close radial side of an ultrasound transducer tip via an opening substantially aligned with the distal end of the ultrasound transducer tip, as recited by Applicant's Claim 1. Further, von Gutfeld et al. does not disclose or suggest a fluid source for introducing a fluid to a distal radiation surface of a transducer via an opening substantially aligned with the distal radiation surface of the transducer to produce a spray, as recited by Applicant's Claim 50. Accordingly, withdrawal of the rejection under 35 U.S.C. §102(b) and allowance of Claims 1 and 50 are respectfully requested.

Claims 4, 6, 14, 21, 23, 25, 51 and 52 depend from Claims 1 and 50, and therefore include the limitations of Claims 1 and 50. Accordingly, for the same reasons given for Claims 1 and 50, Claims 4, 6, 14, 21, 23, 25, 51 and 52 are believed to contain patentable subject matter.

Accordingly, withdrawal of the rejection under 35 U.S.C. §102(b) and allowance of Claims 4, 6, 14, 21, 23, 25, 51 and 52 are respectfully requested.

Claims 32 and 40-42 were rejected under 35 U.S.C. §103(a) as being unpatentable over von Gutfeld et al.

Claims 32 and 40-42 depend from Claim 1, and therefore include the limitations of Claim 1. Accordingly, for the same reasons given for Claim 1, Claims 32 and 40-42 are believed to contain patentable subject matter. Accordingly, withdrawal of the rejection under 35 U.S.C. §103(a) and allowance of Claims 32 and 40-42 are respectfully requested.

The Examiner further rejected Claims 1, 4, 6, 14, 21, 23, 25, 32, 40-42 and 50-52 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-8; 13-20; and 14-24 of U.S. Patent Nos. 5,076,266; 6,478,754; and 6,533,803, respectively. The rejection with respect to Claims 1-8 of U.S. Patent No. 5,076,266 (the '266 patent) is respectfully traversed.

U.S. Patent No. 5,076,266 is directed to a device for ultrasonic atomizing of a liquid medium comprising an ultrasonic vibrator (1) with a concentrator (2) whose terminal portion (4) accommodates a bell mouth (24) which serves as a means for regulating the liquid medium spray cone angle. Main, additional, and auxiliary thrust bushings (3,5,6) are installed on the ultrasonic vibrator (1) and concentrator (2). Arranged along the concentrator (2) are a branch pipe (9) for feeding a liquid medium and a guide (8) mechanically connected with the main and additional thrust bushings (3 and 5) whose free ends extend through respective hollow rods (15 and 16) mechanically linked with the auxiliary thrust bushing (6).

Claim 1 of the '266 patent recites:

A device for ultrasonic atomizing of a liquid medium, comprising: an ultrasonic vibrator (1) communicating with a concentrator (2); a main thrust bushing (3) wherein the ultrasonic vibrator (1) is mounted; an additional thrust bushing (5) encompassing the concentrator (2); an auxiliary thrust bushing (6) whose body has a radial channel (17) whose outlet is on an internal surface (21) of the bushing which encompasses a terminal portion (4) of the concentrator (2);

a guide (8) mechanically connected with the main and additional thrust bushing (3 and 5) and having a free guide end;

a branch pipe (9) to feed a liquid medium, which is arranged along a geometrical longitudinal axis (7) of the concentrator (2), and is mechanically connected to the main thrust bushing, (3) and has a free end (12) extending through the additional thrust bushing (5);

two hollow rods (15,16) each having one end mechanically connected with the auxiliary thrust bushing (6) and having distal ends (13, 14) into which are movably inserted the free end of the guide (8) and the branch pipe (9) wherein the rod, into which the branch pipe is inserted, is associated with the radial channel (17) for feeding a liquid medium to the terminal end of the concentrator; and

a means for regulating a liquid medium spray cone angle, which arranged concentric with and on said terminal portion (4) of the concentrator (2) to provide a uniform spray with a selected cone angle.

It is Applicant's belief that at least the underlined portions of Claim 1 of the '266 patent recite patentably distinct features over features recited by the presently pending and not withdrawn claims. Additionally, the device disclosed and claimed by Claims 1-8 of the '266 patent is not a nozzle as Applicant's instant invention as recited by Claims 1, 4, 6, 14, 21, 23, 25, 32 and 40-42 of the present application.

It is also Applicant's belief that dependent Claims 2-8 of the '266 patent also recite patentably distinct features over features recited by the presently pending and not withdrawn claims. In particular, Claims 2-8 recite structurally unique features to the device disclosed by the '266 patent.

From a different perspective, Applicant's pending and not withdrawn independent claims also recite patentably distinct features over Claims 1-8 of the '266 patent. Applicant's Claim 1 recites as follows:

A nozzle for ultrasound wound treatment, for producing a spray of liquid using an ultrasound transducer tip, directing and delivering said spray onto the wound surface, comprising: a main body having a proximal end that removably attaches to an ultrasound transducer, said main body also having a distal end which

is marginally close to a free distal end of the ultrasound transducer tip, said distal end of said main body having a gap with said distal end of said ultrasound transducer tip, said distal end of main body being coaxially placed about the said ultrasound transducer tip, said main body being connected with at least one reservoir, for holding and delivering a wound treatment solution to the distal end or the marginally close radial side of said ultrasound transducer tip via an opening substantially aligned with the free distal end of the ultrasound transducer tip. (Emphasis added)

It is Applicant's belief that at least the underlined portions recite features of Applicant's invention that are patentably distinct over features recited by Claims 1-8 of the '266 patent. That is, the features of a nozzle for ultrasound wound treatment comprising a main body having a proximal end that removably attaches to an ultrasound transducer having an ultrasound transducer tip, and delivering a wound treatment solution to a distal end or a marginally close radial side of the ultrasound transducer tip via an opening substantially aligned with a free distal end of the ultrasound transducer tip are patentably distinct features over features recited by Claims 1-8 of the '266 patent.

Applicant's Claim 50 recites as follows:

An apparatus for treating a wound comprising: a transducer having a distal radiation surface arranged in proximity to the surface of the wound for emitting ultrasonic energy; and a fluid source for introducing a fluid to the distal radiation surface via an opening substantially aligned with the distal radiation surface of the transducer to produce a spray, wherein the generated ultrasonic energy is delivered to the wound through the spray, and wherein the ultrasonic energy provides a bactericidal and a therapeutic effect for decreasing the healing time for the wound. (Emphasis added)

It is also Applicant's belief that at least the underlined portion recites features of Applicant's invention that are patentably distinct over features recited by Claims 1-8 of the '266 patent. That is, the features of a fluid source for introducing a fluid to a distal radiation surface of a transducer via an opening substantially aligned with the distal radiation surface are patentably distinct features over features recited by Claims 1-8 of the '266 patent.

For at least the above-stated reasons, Claims 1, 4, 6, 14, 21, 23, 25, 32, 40-42 and 50-52 of the present application are patentably distinct over Claims 1-8 of the '266 patent.

Accordingly, withdrawal of the obviousness-type double patenting rejection with respect to Claims 1, 4, 6, 14, 21, 23, 25, 32, 40-42 and 50-52 over Claims 1-8 of the '266 patent is respectfully requested.

With respect to the obviousness-type double patenting rejection of Claims 1, 4, 6, 14, 21, 23, 25, 32, 40-42 and 50-52 over U.S. Patent Nos. 6,478,754 and 6,533,803, Applicant agrees with the Examiner's assessment as outlined on paragraph 12 of the Office Action. Therefore, Applicant submits two terminal disclaimers along with this amendment in compliance with 37 C.F.R. Sec. 1.321(c), since the present application and U.S. Patent Nos. 6,478,754; and 6,533,803 are commonly owned. Each terminal disclaimer corresponds to one of the two patents commonly owned with the present application.

The subject matter of new independent Claim 59 is patentably distinct from the teachings of von Gutfeld et al. for at least the reasons given above for independent Claims 1 and 50.

Further, the nozzle claimed by new independent Claim 59 is structurally different from the tool disclosed by von Gutfeld et al. In particular, von Gutfeld et al. does not disclose or suggest "a housing dimensioned for housing at least a portion of the ultrasound transducer and for delivering the ultrasonic spray towards a wound surface," as recited by Applicant's Claim 59.

The housing 20 of the tool disclosed by von Gutfeld et al. is not dimensioned for delivering ultrasonic spray, since the transducer means 16 sonicates the liquid to create a sonicated liquid stream. Therefore, as mentioned above, the tool of von Gutfeld et al. delivers a sonicated liquid stream, and not a spray. Accordingly, allowance of new independent Claim 59 is respectfully

requested.

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims presently pending in the application and not withdrawn from consideration, namely, Claims 1, 4, 6, 14, 21, 23, 25, 32, 40-42, 50-52, and 59, are believed to be in condition for allowance and patentably distinguishable over the art of record.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call Applicant's undersigned attorney at (631) 501-5706.

Respectfully submitted,

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